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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,463	03/08/2001	Nadia Avalle	P66420US0	4904

7590

06/04/2002

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EXAMINER

WILLIS, MICHAEL A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/800,463

Applicant(s)

AVALLE, NADIA

Examiner

Michael A. Willis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 5 and 14 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed/on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendments of 5 November 2001 and 14 November 2001 are entered.

Claims 1-3 and 6-17 are pending. Any previous rejections that are not restated in this Office Action are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

All previous rejections under 35 USC 102(e) or 35 USC 103(a) are withdrawn.

Claims 7 and 12 are rejected under 35 USC 112, 2<sup>nd</sup> paragraph, due to the phrase "functional substances" for reasons as stated previously. Applicant argues that the phrase is defined in the specification at page 4, lines 5 and 19. However, the cited passages merely state that the "polymer/co-polymer phase can also incorporate lipid/hydrophilic functional substances" and further gives three examples of functional substances that are aggregable with the polymer/co-polymer phase. The three examples given do not appear to define the phrase "functional substances". It is not clear if functional substances are meant to be biologically active agents, or surface-active agents, or some other type of agent altogether. As such, the metes and bounds of the phrase "functional substances" are unclear.

The following new grounds of rejection are made:

***Claim Rejections - 35 USC § 112***

Claims 1-3 and 6-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for being vague and indefinite due to the phrase “silica derivatives”. While the specification describes the use of spherical and non-spherical silica, it is unclear if the phrase “silica derivatives” is limited to these two groups of silica, or if the phrase includes other compounds. Therefore the metes and bounds of the phrase are unclear.

Claim 10 is rejected for being confusing because the version of claim 10 submitted in the supplementary amendment of 14 November 2001 is word-for-word the same as the version of claim 10 submitted 5 November 2001 that it is supposed to replace. Claim 10 is also rejected for being indefinite due to the phrase “silicones and silicone derivatives”. It is unclear how “silicone derivatives” differ from silicones. Since the specification does not define “silicone derivatives”, the metes and bounds of the phrase are unclear, and one of ordinary skill in the art would not be apprised of the scope of the claim.

Any remaining claims are rejected for depending from an indefinite base claim.

***Claim Rejections - 35 USC § 102***

Claims 1-3, 6-7, 9, and 14-17 are rejected under 35 U.S.C. 102(e) as being unpatentable over Elwakil (US Pat. 6,187,439). Elwakil teaches encapsulated pigments

(see abstract and col. 5, lines 31-67). Polymers used to encapsulate the pigments include polymers of lactic acid or glycolic acid (see col. 11, lines 4-26. While the field of endeavor of Elwakil is admittedly different from the field of endeavor of the instant application, the term "cosmetic" in the preamble of the instant claims is not given patentable weight. The encapsulated pigments are present in 1-90% by weight of the final products (see col. 11, lines 51-55).

***Claim Rejections - 35 USC § 103***

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gustafsson et al (US Pat. 6,120,787). Gustafsson teaches sustained release microparticles (see abstract). The preferred core material for the microparticles is starch (see col. 4, lines 44-45). The specification clearly indicates that starch meets the limitation of an excipient (see page 4, lines 10-12 of the instant application). Preferred polymers include lactic acid or glycolic acid monomers (see col. 4, lines 53-63). Additives can also be included in the polymer shell (see col. 6, lines 10-25). Ascorbic acid, also known as vitamin C, is listed. Ethyl acetate is used in the procedure for applying the coating to the particles (see col. 10, lines 15-45). The reference lacks teaching the weight percentages of components in the final compositions. While the reference is silent regarding % by weight of the particles in the final compositions, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are

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disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on alternate Mon. and Tues. to Fri. from 9am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis  
Examiner  
Art Unit 1617

June 3, 2002



MICHAEL G. HARTLEY  
PRIMARY EXAMINER